38. (AMENDED) The method of claim 16 wherein the instrument is manipulated by a robotic apparatus.

a12 cont.

39. (AMENDED) The method of claim 16 wherein the imaging device is a CT, MRI or ultrasound device.

REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-42 are pending in the subject application. Claims 1-3, 16-18 and 40-42 stand rejected under 35 U.S.C. §102 and claims 4-15 and 19-39 were objected to under Rule 75(c).

Claims 4-8, 10-11, 13-15, 19-21, 24, 26-33, 35 and 37-39 were amended to address the Examiner objection under Rule 75(c) to the form of the multiple dependent claims. The amendments to the claims are supported by the originally filed disclosure.

The specification was objected to and correction required. The drawing figures were objected to and correction required. The specification was amended to address the Examiner's objections and/or rejections. An amendment is filed herewith to address one of the drawing objection(s) and the specification is amended in the foregoing to address another of the drawing objection(s). The amendment(s) to the specification does not introduce new matter because they either are editorial in nature or are supported by the originally filed disclosure.

Included herewith is a marked-up version of the amendments to the subject application by the current amendment. The marked-up versions are found on the pages captioned or entitled

"Details of Amendments" that follow the signature page of the within Response.

35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 1-3, 16-18 and 40-42 35 U.S.C. §102(b) as being anticipated by Dumoulin [USP 5,318,025]. Applicants respectfully traverse as discussed below.

The above-referenced of this action asserts that Dumoulin discloses a tracking system to monitor the position and orientation of a device such as catheter by using magnetic resonance detection. It also is asserted that the flexible device in Dumoulin contains intermediate sensors and a sensor proximate the distal tip, where the sensors are RF coils that detect MR signals that are generated in response to a controlled 3-dimensional magnetic field generated by a set of gradient coils. It is further asserted that these RF coils in combination with the disclosed processing and calculating means provide identifiable points for all of the coils and the unique orientation of the device within its range of motion. Applicants respectfully submit that although Dumoulin apparently discloses a tracking system, it does not disclose the tracking system as is claimed by Applicants.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the

claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the following remarks that claim 1 is not anticipated by Dumoulin. It also is respectfully submitted that the following remarks also make clear that there is no teaching nor suggestion of the claimed invention provided in Dumoulin. It is further submitted, that there is no teaching, suggestion nor any motivation offered in Dumoulin for modifying the imaging system described therein so as to yield the imaging system as set forth in claim 1.

Applicant claims, claim 1, an imaging system for invasive therapy of a patient, the system that includes an imaging apparatus that can provide a cross-sectional image of a patient, and a medical instrument, which medical instrument includes a fiducial object that can be imaged *in the same image* as a targeted site of the patient.

As indicated in the subject application (e.g., see page 4, thereof) such a system provides a mechanism by which the three-dimensional position and orientation of a medical instrument (effector) such as a needle, probe, etc. relative to a subject using one or more cross sectional images of the subject can be determined so as to enable effector placement without use of patient immobilization or separate fiducial implantation. In addition, by placement of a fiducial object separate from a patient but in association with a medical instrument, a single cross-sectional image can be taken via an imaging device such as Computed Tomography, Magnetic Resonance Imaging or ultrasound, and that single image can be employed to directly manipulate and orient the medical instrument during the course of a surgical procedure.

It appears that the grounds for the within rejection are premised on the assumption, albeit an incorrect assumption, that because the tracking system in Dumoulin employs magnetic resonance

signals to monitor the position and orientation of a device such as a catheter within a subject (see Abstract), such a tracking system necessarily localizes the device using cross-sectional images generated using the MRI process. While it is correct that the MRI process or technique can be used to generate cross-sectional images of a targeted site within a subject, the magnetic resonance imaging technique/process has nothing to do with the tracking technique described and taught in Dumoulin for localizing the RF coils/sensors affixed to the device when disposed within the subject.

As is known to those skilled in the art, Dumoulin describes and teaches a tracking technique whereby a short series of RF and gradient pulses are used to locate the RF coils/sensors. This tracking process/ technique does *not* involve generating an image, much less generating a cross-sectional image of the targeted site of the subject. In Dumoulin, and in an entirely separate step from that involved with the tracking process, a cross-sectional image is acquired using any one of the enumerated techniques disclosed in Dumoulin, including the MRI technique. The location of this cross-sectional image presumably is chosen based on the determined location of the RF coils/sensors.

Dumoulin further indicates that in the preferred embodiment, the position and orientation of the device is displayed on the display means by *superposition* of a graphical symbol on a conventional MR image driven by a superposition means. In alternative embodiments, it also is indicated that the graphical symbol representing the device is *superimposed* on diagnostic images obtained with other medical imaging systems such as a CT scanner, a positron emission tomography system or UT scanner. It is further indicated that since such other medical imaging

systems do not interfere with the MR tracking process, these other imaging systems can be operated during the steps of MR tracking. It necessarily follows that the MR imaging process/ technique for generating cross-sectional images would interfere with the MR tracking process used in Dumoulin.

In contrast, in the claimed present invention localization of the medical device is achieved based on information derived or obtained based on the fiducial object appearing in the cross-sectional image. In other words, cross-sectional imaging and localization are tied together. Whereas in Dumoulin, any cross-sectional images generated using any of the enumerated imaging techniques disclosed therein provide no information as to the location of the device within the subject.

As set forth in claim 1, an imaging system according to the present invention includes an imaging apparatus that can provide a cross-sectional image of a patient and a medical device that includes a *fiducial object* that can be imaged in the same image as a targeted site of the patient. Dumoulin nowhere discloses a medical device that includes a fiducial object, as that term is used by those skilled in the art. Moreover, Dumoulin also nowhere discloses that the fiducial object being included with the medial device is such that the fiducial object can be imaged in the same image, the cross-sectional image of the patient obtained by the imaging apparatus, at the target site of the subject/ patient.

As indicated above, Dumoulin describes a tracking system or tracking technique in which the device is configured with a plurality of RF coils/ sensors. It is clear from the subject application, that a fiducial object is not an image sensing device but rather in general terms is a structural feature that is visible in the particular imaging process (e.g., MRI process) and which is

used to provide one or more points of reference so that the pose of the medical device can be determined (e.g., see page 3 of the subject application). In contrast to the present invention where the medical device includes the fiducial object, and as described in the subject application, with known surgical techniques fiducial markers are affixed to the bones of the patient to provide fixed points of references. In sum, the RF coils/ sensors disclosed in Dumoulin cannot be said to correspond to a fiducial object being affixed to a medical device as set forth in the claimed invention.

Moreover, and as indicated above, the fiducial object being included with the medical device is such that the fiducial object can be imaged in the same image as a targeted site of the patient. The Abstract in Dumoulin makes abundantly clear that in the invention described in Dumoulin, the position and orientation of the device is superimposed upon *independently acquired medical diagnostic images*. See also the discussion above regarding use of the MR tracking device in connection with non-MR imaging systems. It necessarily follows that Dumoulin cannot further disclose, teach or suggest a medical device having a fiducial object in which the fiducial object can be imaged in the same image (i.e., the cross-sectional image of the patient) as a targeted site of the patient. As indicated above, in Dumoulin the generation of cross-sectional images and the particular imaging technique for generating such images is completely separate from the technique and process utilized to track or localize the device within the subject that is described and taught in Dumoulin.

Although the claims dependent from claim 1 are considered allowable at least because of their dependency from a claim which is conceded to be allowable, applicants make the following

further observations as to the patentability of certain of the pending dependent claims from the cited reference.

Claim 3 further provides that the image, namely the obtained cross-sectional image of the patient can produce three (3) identifiable points to coordinate pose of the instrument and the targeted site of the patient. This is nowhere disclosed, taught or suggested in Dumoulin.

Claim 8 further provides that the fiducial object comprises three (3) N-shaped fiducial motifs, and additionally that the three N-shaped fiducial motifs are non-coplanar. In addition, claim 9 adds the further limitation that these three N-shaped motifs are arranged so as to form a U-shape in which one such motif forms the bottom and the other two motifs the sides. This is nowhere disclosed, taught or suggested in Dunmoulin.

As has been indicated by the Federal Circuit, in deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify *corresponding elements* disclosed in the allegedly anticipating reference (emphasis added, citations in support omitted). *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, 730 F. 2d 1452, 221 USPQ 481,485 (Fed. Cir. 1984). In concluding that the `770 Patent did not anticipate the claims, the Federal Circuit in *Lindemann Maschinenfabrik GMBM v. American Hoist and Derrick Company et al.*, at 221 USPQ 485-486, further provides that:

> The `770 patent discloses an entirely different device, composed of parts distinct from those of the claimed invention, and operating in a different way to process different materials differently.

> Thus, there is no possible question of anticipation by equivalents.
>
> Citations omitted.

It is clear from the foregoing remarks, that the allegedly corresponding elements disclosed in Dumpulin do not in fact correspond to the elements of the claimed invention. It also is clear that the imaging system/ tracking system described in Dumoulin functions and operates in a different manner from that of the claimed invention. As also indicated above, the method disclosed and taught in Dumoulin for tracking or localizing a medical device within a subject is completely different from that claimed and taught by Applicants. Thus, there can be no disclosure or teaching in Dumoulin of Applicants' invention.

It is respectfully submitted that the foregoing remarks regarding claim 1 apply equally to distinguish independent claim 16 from the cited reference.

It is respectfully submitted that the foregoing remarks regarding claims 1 and 3 apply equally to distinguish independent claims 40-42 from the cited reference.

It is respectfully submitted that for the foregoing reasons, claims 1-3, 16-18 and 40-42 are patentable over the cited reference and, therefore, satisfy the requirements of 35 U.S.C. §102(b). As such, these claims, including the claims dependent therefrom are allowable.

CLAIMS 4-15 & 19-39

Claims 4-15 and 19-39 were objected to in the above-referenced Office Action as not being in proper form for a multiple dependent claim.

As indicated above claims 4-8, 10-11, 13-15, 19-21, 24, 26-33, 35 and 37-39 were amended to address the Examiner's objection to the claims under Rule 75(c). As to claims 9, 12, 22-23, 25, 34 and 36, these claims are not multiple dependent claims, but appear to have been objected to because they depend from a multiple dependent claim listed above. Applicant thus believes that amendment of these claims is not required to address the within objection.

It is respectfully submitted that each of claims 4-15 and 19-39 are also distinguishable from the cited prior art upon which the above-described rejections were based upon.

It is respectfully submitted that the above-identified claims satisfy Rule 75 and thus are considered to be in acceptable form.

SEPCIFICATION OBJECTIONS

The Examiner objected to the specification of the subject application for the reasons provided on pages 2-3 of the above-referenced Office Action and requested correction thereof. The following addresses the specific objections of the Examiner.

Applicants amended the specification as suggested by the Examiner.

As also indicated below, the specification was amended to address certain of the objections directed to the drawing figures.

It is respectfully submitted that for the foregoing reasons, the specification satisfies applicable Patent laws and rules and, therefore is considered acceptable.

DRAWING OBJECTIONS

The Examiner objected to the drawing figures for the reasons set forth on page 2 of the above referenced Office Action and requested correction of same.

As to the objection based on the use of reference numerals "114" and "115" to designate the image plane, Applicants have amended page 11 of the subject application, so that reference numeral 115 is used to designate the image plane. Reference numeral 114, as indicated on page 7 of the subject application is used to designate a single image.

The other objection is based on the presence of reference sign(s) 214, p1, p2 and p3 in the description but not being shown on the drawing figures. Applicants have reviewed the subject application and have not identified an occurrence of 214, p1, p2 and p3, however, Applicants presume that the Examiner is referring to the occurrence on page 11 of p1, p2 and p3 in proximity to reference numeral 214.

As indicated in the subject application (e.g., see page 11 thereof), p1, p2 and p3, are the three fiducial bar *points of intersection* with the image plane 115. These points of intersection with the three fiducial bars are shown in FIG. 3B. Although further amendment of the drawing figures is not believed to be required in view of the description provided in the subject application, Applicants are submitting herewith a drawing amendment for clarity that amends FIG. 3B so as to identify these points of intersection using reference numerals p1, p2, and p3.

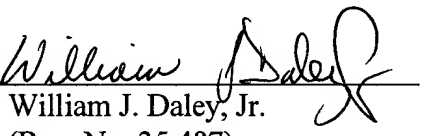
In view of the foregoing amendment to the specification and the amendment to the drawing figures being submitted herewith, the drawing figures, as amended, are considered acceptable.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
EDWARDS & ANGELL, LLP
DBRC Intellectual Property Practice Group

Date: December 10, 2002

By: 

William J. Daley, Jr.
(Reg. No. 35,487)
P.O. Box 9169
Boston, MA 02209
(617) 439- 4444

DETAILS OF AMENDMENTS

Please amend the subject application as follows:

IN THE SPECIFICATION

Page 1, rewrite the paragraph starting at line 8, to read as follows:

The present invention relates to methods and systems for image-guided effector placement. Methods and systems of the invention ~~of the invention~~ enable minimally invasive image-guided interventions with a single cross-sectional image and without the use of a sterotactic frame or separate fidicucial apparatus. Preferred systems of the invention include a localization module, integrated with a medical instrument, that allows for localization of the effector in targeted image space using a single cross-sectional image.

Page 3, rewrite the paragraph starting at line 19, to read as follows:

It thus would be desirable to have improved methods and systems to determine the location of an end effector delivery system and the location of an effector such as a needle, probe, etc. within a body. It would be further desirable to have such a position and orientation system that could be employed in minimally invasive surgical procedures without need for external reference frames, surgically implanted fiducial markers or calibration procedures.

Page 8, rewrite the paragraph starting at line 15, to read as follows:

As discussed above, a registration system is provided for determining the three-dimensional position and orientation of an effector such as a needle, probe, etc. relative to a subject using one or

more cross sectional images of the subject. The image registration system suitably comprises a scanning device such as a CT, MRI or the like, and a fiducial object (i.e. that can be detected by the imaging apparatus) associated with a surgical instrument. Systems and methods of the invention enable effector placement without use of patient immobilization or separate fiducial implantation.

Page 11, rewrite the paragraph starting at line 7, to read as follows:

A schematic illustration of one fiducial motif 214 intersected by an image plane 115 is presented in FIG. 3B wherein p_1, p_2, p_3 are the three fiducial bar points of intersection with the image plane 115. The orientation of the image plane 115 relative to the fiducial motif 214 is described by three parameters by f, the fraction of the distance along the diagonal fiducial where the intersection occurs; ϕ, the angle between the fiducial motif plane 214 and the image plane ~~114~~115; and θ, the angle between the parallel fiducial bars and the line of intersection.

IN THE CLAIMS

Amend claims 4-8, 10-11, 13-15, 19-21, 24, 26-33, 35 and 37-39 to read as follows:

4. (AMENDED) The system of ~~any one of~~ claims 1 ~~through 3~~ wherein the instrument pose is directly manipulated in reference to the medical image.

5. (AMENDED) The system of ~~any one of~~ claims 1 ~~through 4~~ wherein the relative position and orientation of the medical instrument and target site of the patient can be determined from the information contained in a single cross-sectional image produced by the imaging apparatus.

6. (AMENDED) The system of ~~any one of~~ claims 1 ~~through 5~~ wherein the system

comprises a control apparatus that can register the instrument in a detected image space and calculate instrument movement.

7. (AMENDED) The system of ~~any one of~~ claims ~~1 through~~ 6 wherein the control apparatus calculates the instrument pose in the image space by generating at least three corresponding points.

8. (AMENDED) The system of ~~any one of~~ claims 1 ~~through 7~~ wherein the fiducial object comprises three N-shaped fiducial motifs, and the three N-shaped fiducial motifs are non-coplanar.

10. (AMENDED) The system of ~~any one of~~ claims 1 ~~through 9~~ wherein the medical instrument is manipulated manually.

11. (AMENDED) The system of any one of claims 1 through 10 wherein the system further comprises a robotic apparatus capable of positioning the apparatus.

13. (AMENDED) The system of ~~any one of~~ claims 1 ~~through 12~~ wherein the imaging device is a CT, MRI or ultrasound device.

14. (AMENDED) The system of ~~any one of~~ claims 1 ~~through 13~~ wherein the fiducial object is affixed to the instrument.

15. (AMENDED) The system of ~~any one of~~ claims 1 ~~through~~ 14 wherein the fiducial object is integral to the instrument.

19. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 18~~ wherein the instrument is manipulated substantially contemporaneously with respect to obtaining the image.

20. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 19~~ wherein the instrument is manipulated based on a single image.

21. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 20~~ wherein a plurality of images are obtained.

24. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 23~~ wherein a material is deposited or administered to the patient by the instrument.

26. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 25~~ wherein energy is administered to the patient.

27. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 22~~ wherein energy is removed from the patient.

28. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 25~~ wherein tissue is removed from the patient by the instrument.

29. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 28~~ wherein the instrument administers to the patient a radiation seed implant, a DNA therapeutic, a chemotherapeutic agent, a cryotherapeutic treatment, a sclerotic solution, ethanol, high intensity ultrasound, directed beam therapy, localized X-ray therapy, photodynamic therapy, laser ablation therapy, or RF ablation therapy.

30. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 29~~ wherein the fiducial object representation in the image is unique for the pose of the instrument.

31. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 30~~ wherein the image can produce three identifiable points to coordinate pose of the instrument and the targeted site of the patient.

32. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 31~~ wherein the instrument pose is directly manipulated in reference to the medical image.

33. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 32~~ wherein the instrument is registered in detected image space by a control apparatus.

35. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 34~~ wherein the fiducial object comprises three N-shaped fiducial motifs, and the three fiducial motifs are non-coplanar.

37. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 36~~ wherein the medical instrument is manipulated manually.

38. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 36~~ wherein the instrument is manipulated by a robotic apparatus.

39. (AMENDED) The method of ~~any one of~~ claims 16 ~~through 38~~ wherein the imaging device is a CT, MRI or ultrasound device.